K132886

510(k) Summary of Safety and Effectiveness

FEB - 4 2014

Smith & Nephew Variable-Angle Locking Mini-Fragment Plating System

Submitted By:	Smith & Nephew, Inc. Orthopaedic Division 1450 Brooks Road Memphis, TN 38116
Date Prepared:	December 27, 2013
Contact Person:	David Henley, Regulatory Affairs Project Manager Tel: (901) 399-6487 Fax: (901) 566-7079
Proprietary Name:	**Smith & Nephew Variable-Angle Locking Mini-Fragment Plating System**
Common Name:	Bone Plates, Bone Screws and Washers
Classification Name and Reference:	21 CFR 888.3030, Single/multiple component metallic bone fixation appliances and accessories - Class 2 21 CFR 888.3040, Smooth or threaded metallic bone fixation fastener - Class 2
Device Product Code and Panel Code:	HRS / HWC / HTN Orthopedics / 87

Device Description:

The subject **Smith & Nephew Variable-Angle Locking Mini-Fragment Plating System** is an internal fixation plating system comprised of assorted small. implantable utility *locking bone plates* and compatible *locking* and *non-locking bone screws* and *washers* to be used on various small bones and small bone fragments and non-load bearing stabilization and reduction of bone fragments in long bones. Plates consist of groups of devices with a flat cross-section and others with a radiused cross-section where the number of holes in plates will range from 4 through 20. All described implant devices are manufactured from implant-grade titanium alloy material and will be available in a sterile or non-sterile packaged condition.

Intended Use:

Bone plates and bone screws from the Smith & Nephew Variable-Angle Locking Mini-Fragment Plating System are intended for use in internal fixation of small bones and small bone fragments and non-load bearing stabilization and reduction of bone fragments in long bones.

Indications for Use:

The Smith & Nephew Variable-Angle Locking Mini-Fragment Plating System is indicated for adolescent (12-18 years) and transitional adolescent (18-21 years) subpopulations and adults, as well as patients with osteopenic bone. The Smith & Nephew Variable-Angle Locking Mini-Fragment Plating System is indicated for fracture fixation, arthrodesis, reconstruction, replantation or reduction of small bones and small bone fragments. This system is also indicated for non-load bearing stabilization and reduction of bone fragments in long bones.

Implantable bone plates, bone screws and washers from the Smith & Nephew Variable-Angle Locking Mini-Fragment Plating System are for single use only.

Technological Characteristics:

Device comparisons described in this premarket notification demonstrated that the proposed bone plates, bone screws and washers are substantially equivalent to the legally marketed predicate devices (listed below) with regard to intended use, indications for use, materials and performance characteristics.

Substantial Equivalence Information:

When compared to the predicate devices listed below, substantial equivalence is based *similar* intended use, indications for use, raw materials, operating principles and design/performance characteristics.

- Smith & Nephew Bone Plate System (TC-100 Plating and Screw System) – K993106
- VLP Foot Plating and Screw System – K090675
- PERI-LOC (Titanium) Bone Plating and Screw System – K083032
- Smith & Nephew 6.5mm and 8.0mm Cannulated Screws – K060736
- PERI-LOC B-Plate Locking Bone Plates and Screws – K062216
- Synthes Modular Mini Fragment LCP System – K063049
- Medartis APTUS Titanium System – K051567
- DePuy ALPS Small Bone Locked Plating System – K101240
- Hand Innovations LLC, Mini Fragment Plates – K061748

Non-clinical Testing:

To further support a determination of substantial equivalence, non-clinical bench (mechanical) testing was conducted on bone plates and screws from the Smith & Nephew Variable-Angle Locking Mini-Fragment Plating System. Test results demonstrated that the proposed devices are substantially equivalent to one or more of the previously cleared predicate devices described above. The specific type of non-clinical testing conducted is described as:

- Finite element analysis (FEA) of bone plates to predict the worst-case plate for subsequent non-clinical bench (mechanical) testing
- Four-point bend fatigue testing of bone plates and bone screws
- Torque-to-failure testing of bone screws
- Axial pull-out testing of bone screws

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 4, 2014

Smith & Nephew, Incorporated
Mr. David Henley
Regulatory Affairs Project Manager
1450 Brooks Road
Memphis, Tennessee 38116

Re: K132886
Trade/Device Name: Smith & Nephew Variable-Angle Locking Mini-Fragment Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC, HTN
Dated: December 27, 2013
Received: December 30, 2013

Dear Mr. Henley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Vincent J. Devlin -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Premarket Notification
Indications for Use Statement

K132886

510(k) Number (if known): _____

Device Name: Smith & Nephew Variable-Angle Locking Mini-Fragment Plating System

Indications for Use:

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Components in the Smith & Nephew Variable-Angle Locking Mini-Fragment Plating System are for single use only.

Prescription Use _____X_____ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth D. Frank -S

Division of Orthopedic Devices